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In the Supreme Court of the United States

LOUISIANA WHOLESALE DRUG CO., INC., CVS PHARMACY, INC., RITE AID CORPORATION, ARTHUR'S DRUG STORE, INC.,

Petitioners,

v.

BAYER AG, BAYER CORP., formerly doing business as Miles Inc., HOECHST MARION ROUSSEL, INC., THE RUGBY GROUP, INC., WATSON PHARMACEUTICALS, INC., BARR LABORATORIES, INC.,

Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Second Circuit

BRIEF *AMICUS CURIAE* OF AARP IN SUPPORT OF PETITIONERS

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STATEMENT OF INTEREST OF *AMICUS CURIAE*[1]

AARP is a nonpartisan, nonprofit organization dedicated to addressing the needs and interests of people aged fifty and older. AARP has a long history of advocating for access to affordable health care and for controlling costs without compromising quality. Affordable prescription medication is particularly important to the older population which, because of its higher rates of chronic and serious health conditions, has the highest rate of prescription drug use. Persons over sixty-five, although only thirteen percent of the population, account for thirty-four percent of all prescriptions dispensed and forty-two cents of every dollar spent on prescription drugs. Families USA, *Cost Overdose: Growth in Drug Spending for the Elderly*, 1992-2010 at 2 (July 2000).

Significantly, in a 2005 AARP survey, one in four Americans, ages 50 and older, who took a prescription drug in the past five years said they did not fill a prescription written by their doctor in the past two years. Cost was reported as the main deterrent. Linda L. Barrett, Ph.D., *Prescription Drug Use Among Midlife and Older Americans,* AARP

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[1] In accordance with Supreme Court Rule 37.6, *Amicus Curiae* states that: (1) no counsel to a party authored this brief, in whole or in part; and (2) no person or entity, other than *amicus*, their members and counsel have made a monetary contribution to the preparation or submission of this brief. Parties were timely informed with 10-days notice of the intent to file this *amicus* brief, and the written consents of the parties to the filing of this brief have been filed with the Clerk of the Court pursuant to Supreme Court Rule 37.3.

(2005), *available at* assets.aarp.org/rgcenter/health/rx_midlife_plus.pdf. Since prescription drug spending has skyrocketed over the last decade and a half, and national health expenditures on prescription drugs have quadrupled, AARP advocates for broader access to prescription drugs and lower prescription drug costs for consumers. *See, e.g.*, AARP, *Rx Watchdog Report* (May 2010), *available at* http://www.aarp.org/health/Drugs-supplements/rx_watchdog.html.

SUMMARY OF ARGUMENT

The ruling below that exclusion payment agreements are with few exceptions *per se* lawful under Section 1 of the Sherman Act will have a devastating impact on American consumers if left to stand. Prescription drug spending in the United States has skyrocketed over the last two decades. Competition from generic drugs is the most effective means of slowing the spiraling cost of pharmaceuticals. Generics typically sell for a fraction of the cost of their branded counterparts and quickly capture the majority of unit sales, thus having saved consumers over $734 billion in the past ten years. Recognizing the clear consumer benefit that accompanies generic drug competition, Congress sought to speed up generic entry by enacting the Hatch-Waxman Act.

Brand-name firms have used exclusion agreements to delay entry of generics an average of seventeen months and to terminate patent challenges that would otherwise generate *billions* of

dollars in consumer savings. Delaying the entry of affordable generic drugs not only prevents competition, but the lack of low cost treatment options reverberates throughout the entire health care system. Even for those patients who are insured but who are on fixed or limited incomes, having a generic option is often the difference between having access to a health care treatment and not having any treatment option at all. Economists at the FTC estimate that, if nothing changes, exclusion payment settlements will cost consumers $35 billion over the next ten years. If *Cipro* remains controlling law, the patent-challenge provisions of the Hatch-Waxman Act would be eviscerated, and American consumers would be left to pay the price.

REASONS FOR GRANTING THE WRIT

INTRODUCTION

The ruling below that exclusion payment agreements are with few exceptions *per se* lawful under Section 1 of the Sherman Act will have a devastating impact on American consumers if left to stand. According to the Second Circuit, the statutory rebuttable presumption of validity enjoyed by patents, 35 U.S.C. § 282, entitles patentees to pay alleged infringers not to contest validity and to stay out of the market.

Competition from generic drugs is one of the few effective means of slowing the spiraling cost of pharmaceuticals. Generics typically sell for a

fraction of the cost of their branded counterparts and quickly capture the majority of unit sales, saving consumers literally millions of dollars on a blockbuster drug such as Bayer Corporation's Cipro. If Barr Laboratories won its patent challenge, it intended to enter the market at a thirty percent discount to the price of brand name Cipro and expected to quickly capture a large percentage of the ciprofloxacin market. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 522 (E.D.N.Y. 2005) (Bayer estimated lost sales of up to $826 million during the first two years of generic competition).

I. THE SECOND CIRCUIT'S DECISION THAT EXCLUSION PAYMENTS ARE *PER SE* LAWFUL DEFEATS THE PROTECTIONS OF THE HATCH-WAXMAN ACT AND UNDERMINES ENFORCEMENT OF THE SHERMAN ACT.

Prescription drug spending in the United States has skyrocketed over the last two decades from $40 billion in 1990 to over $300 billion in 2009. Kaiser Family Foundation, *Prescription Drug Trends*, (Sept. 2008), *available at* http://www.kff.org/rxdrugs/upload/3057_07.pdf; Press Release, IMS Health, *IMS Health Reports U.S. Prescription Sales Grew 5.1 Percent in 2009, to $300.3 Billion*, Apr. 1, 2010, *available at* http://www.imshealth.com/portal/site/imshealth/menuitem.a46c6d4df3db4b3d88f611019418c22a/?vgnextoid=d690a27e9d5b7210VgnVCM100000ed152ca2RCRD&vgnextchannel=41a67900b55

a5110VgnVCM10000071812ca2RCRD&vgnextfmt=default.

In the twelve month period ending with March 2010, the price of brand name prescriptions most widely used by Medicare beneficiaries increased by 9.7 percent, the highest rate of increase observed since AARP began tracking these prices in 2002. AARP, *Rx Watchdog Report: Brand Name Drug Prices Continue to Climb Despite Low General Inflation Rate*, (May 2010), *available at* http://assets.aarp.org/rgcenter/ppi/health-care/i43-watchdog.pdf. Competition from generic drugs is the most effective means of slowing the spiraling cost of pharmaceuticals. Generics typically sell for a fraction of the cost of their branded counterparts and quickly capture the majority of unit sales, thus having saved consumers over $734 billion in the past ten years. AARP, *Rx Watchdog Report*, Vol.6, Issue 4 (May 2009), *available at* http://assets.aarp.org/www.aarp.org_/cs/health/205256rxwatchdogmay09.pdf.

Recognizing the clear consumer benefit that accompanies generic drug competition, Congress sought to speed up generic entry by enacting the Drug Price Competition and Patent Term Restoration Act, 21 U.S.C. § 355, commonly referred to as the Hatch-Waxman Act, which "institutionalize[d] and provide[d] incentive for a system of attacks on presumptively valid patents" by generic manufacturers. *Innovation and Patent Law Reform: Hearings on H.R. 3285, H.R. 3286, and H.R. 3605 Before the Subcomm. on Courts, Civil Liberties,*

and the Administration of Justice of the H. Comm. on the Judiciary, 38th Cong. 2d Sess., Part 1, at p. 444 (1984).

In creating the incentive to challenge patents, Congress was not seeking simply to line the pockets of the generic drug manufacturers. Hatch-Waxman challenges were supposed to be vehicles for earlier entry of generic drugs into the marketplace, thus giving consumers earlier access to lower-priced prescription drug alternatives. H. Rep. No. 98-857, pt. 1 at 1 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647 (explaining that the purpose of the Hatch-Waxman Act "is to make available more low cost generic drugs by establishing a generic drug approval procedure"). Indeed, generics make up nearly seventy percent of drugs prescribed today, whereas generics constituted only twelve percent of prescription drugs dispensed prior to the passage of the Hatch-Waxman Act. *See* AARP, *Rx Watchdog Report*, Vol.6, Issue 4 at 4. *See also*, Food and Drug Administration, *Protecting America's Health Through Human Drugs: Greater Access to Generic Drugs* (Jan. 2006), *available at* http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143545.htm.

The rise of exclusion payment agreements, however, has had a drastic effect on generic drug entry prior to patent expiration. Brand-name firms have used exclusion agreements to delay entry of generics an average of seventeen months and to terminate patent challenges that would otherwise generate *billions* of dollars in consumer savings.

Federal Trade Commission, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* 4 (Jan. 2010), *available at* http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf.

Under the exclusion payment agreement here, for example, Bayer paid its generic competitors $398 million in exchange for the generics' agreement to stay out of the market for 6 1/2 of the remaining 7-year life of the Cipro patent. In other words, Defendants' agreement ensured that consumers would have to wait another 6 1/2 years to buy lower-priced generic ciprofloxacin. This delayed generic entry is the antithesis of what Congress intended when it enacted the Hatch-Waxman Act. *See In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991) ("Congress sought to get generic drugs into the hands of patients at reasonable prices-fast.").

II. INCREASED USE OF EXCLUSION PAYMENTS PREVENTS COMPETITION AND HARMS CONSUMERS.

At the end of 2008, brand name drug manufacturers were attempting to block generic entry on products with roughly $90 billion in pharmaceutical sales. FTC, *Pay-for-Delay*, *supra*, at 9. Delaying the entry of affordable generic drugs not only prevents competition, but the lack of low cost treatment options reverberates throughout the entire health care system. The price of a brand drug can be prohibitive for uninsured patients who do not have help covering the cost of their prescription drugs. Even for those patients who are insured but

who are on fixed or limited incomes, having a generic option is often the difference between having access to a health care treatment and not having any treatment option at all. When a generic pharmaceutical's entry into the market is delayed, it limits treatment access to vulnerable patient populations and prolongs the difficulty that physicians have in prescribing affordable treatment options.

The enormous consumer gains resulting from generic entry are well documented. The Federal Trade Commission (FTC) has found that successful patent challenges to just four major brand-name drugs (Prozac, Zantac, Taxol and Platinol) have saved consumers more than $9 billion. Prepared Statement of the Federal Trade Commission, at 4 (Jan. 17, 2007), *available at* http://www.ftc.gov/speeches/leibowitz/070117Anticompetitivepatentsettlements_senate.pdf. Had exclusion payments been permissible, none of these consumer savings likely would have occurred.

In the midst of Barr Laboratories' challenge to the patents protecting Eli Lilly's drug Prozac, for example, Barr stated that it would settle only if the settlement included an exclusion payment of at least $200 million. *See* Bethany Mclean, *A Bitter Pill*, Fortune, Aug. 13, 2001, at 5. Lilly refused the demand because, as acknowledged by Lilly's CEO, "such a settlement violated antitrust laws, and it isn't morally right." *Id.* So Barr continued litigating the case and ultimately obtained a judgment invalidating the Prozac patents. The resulting early

entry of generic Prozac saved consumers an estimated $2.5 billion. *See* Comment of the Generic Pharmaceutical Ass'n in Support of Citizen Pet., FDA Docket No. 2004P-0075/CP1, at p. 3 (filed May 21, 2004), *available at* http://www.fda.gov/ohrms/dockets/dailys/04/June04/060404/04p-0075-c00003-vol1.pdf.

Allowing exclusion payments that "grant monopoly privileges to the holders of invalid patents," *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 100-01 (1993), results in lost consumer health and welfare greatly disproportionate to the relatively modest costs of patent litigation. *See* Herbert Hovenkamp, *et al.*, *Balancing Ease & Accuracy In Assessing Pharmaceutical Exclusion Payments*, 88 Minn. L. Rev. 712, 717 (2004).

In addition to consumers skipping doses of prescribed medicines due to the high cost of the medicines or co-payments, Barrett, *supra*, a practice known as abandonment, which occurs when a patient refuses to purchase a prescription that was filled by a pharmacist, has been on the rise in 2010. Patients with private health insurance abandoned nearly one in ten new prescriptions for brand-name drugs in the second quarter of 2010. This increase comes as patients see a rise in the cost of prescription medications, like a mother in Montana who arrived at a pharmacy to discover that medication for her depression and her son's asthma would cost her $335 despite her private insurance. The mother abandoned both prescriptions before purchasing a cheaper, alternative medication for her

son. The Wall Street Journal, *More Balk at Cost of Prescriptions*, Oct. 12, 2010 (citing data from a Wolters Kluwer Pharma Solutions study).

When patients do not obtain necessary treatment because no financially feasible options are available, conditions left untreated will worsen and result in a higher cost of care over time. Statement for the Record, American Medical Association, Subcom. on Commerce, Trade, and Consumer Protection for the House Committee on Energy and Commerce, *Impact of "Pay-for-Delay" Settlements On Patient Access to Affordable Generics and Overall Health Care System Costs* (April 13, 2009).

Economists at the FTC estimate that, if nothing changes, exclusion payment settlements will cost consumers $35 billion over the next ten years. FTC, *Pay for Delay, supra*, at 2; *see also* C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 Colum. L. Rev. 629, 650 (2009) (estimating that exclusion payments have already cost consumers over $12 billion).

For this reason, one of the FTC's top priorities is stopping "pay-for-delay" agreements between brand-name pharmaceutical companies and generic competitors that delay the entry of lower-priced generic drugs into the market. FTC Chairman Leibowitz recently noted that, "[a]greements to eliminate potential competition and share the resulting profits are at the core of what the antitrust laws proscribe, and for that reason the Commission

believes strongly that these pay-for-delay settlements are prohibited under the antitrust laws." Jon Leibowitz, Chairman, Fed. Trade Comm'n, *How the Federal Trade Commission Works to Promote Competition and Benefit Consumers in a Dynamic Economy*, Before the Subcomm. on Antitrust, Competition Policy, and Consumer Rights (June 9, 2010) *available at* http://www.ftc.gov/os/testimony/100609dynamiceconomy.pdf.

If *Cipro* remains controlling law, allowing settlements between brand-name and generic firms through exclusion payment agreements, the patent-challenge provisions of the Hatch-Waxman Act would be eviscerated, and American consumers would be left to pay the price.

CONCLUSION

For the foregoing reasons, AARP urges the Court to grant the petition for a *writ of certiorari*.

January 7, 2011 Respectfully submitted,

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